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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Intent to Establish the Tick-Borne Disease Working Group and Solicitation of Nominations for Appointment to the Working Group Membership

AGENCY: U.S. Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health

ACTION: Notice

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces establishment of the Working Group. The Secretary of Health and Human Services is responsible for ensuring the conduct of and support for epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases. The Working Group will assist in this effort. The Working Group will consist of representatives of appropriate federal agencies and non-federal entities who represent diverse scientific disciplines and views. The Working Group will provide expertise and review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. This notice also will serve to announce that HHS is seeking nominations of individuals who are interested in being considered for appointment to the Working Group. Resumes or curricula vitae from qualified individuals who wish to be considered for appointment as a member of the Working Group are currently being accepted.

DATES: Nominations must be received no later than close of business [INSERT DATE 30 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: All nominations should be sent to: CAPT Richard Henry, Office of HIV/AIDS and Infectious Disease Policy; Office of the Assistant Secretary for Health; U.S. Department of Health and Human Services; 330 C Street, S.W., Room L001 Switzer Building; Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: CAPT Richard Henry, Office of HIV/AIDS and Infectious Disease Policy; Telephone: (202) 795-7615; Fax: (202) 691-2101; Email address: richard.henry@hhs.gov. When the charter for the Working Group has been filed with the appropriate Congressional committees and the Library of Congress, this document will be made available online. Website information about activities of the Working Group will be provided when the URL has been identified. The charter will include detailed information about the purpose, function, and structure of the Working Group.

SUPPLEMENTARY INFORMATION: Section 2062 of the 21st Century Cures Act authorizes establishment of the Tick-Borne Disease Working Group (Working Group). The Working Group will be governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The 21st Century Cures Act is intended to advance the research and development of new therapies and diagnostics and make substantial federal investments in a wide range of health priorities.

Under Section 2062 of the 21st Century Cures Act, it is mandated that the Secretary of Health and Human Services establish the Working Group. The Working Group will be comprised of representatives of appropriate federal agencies and non-federal entities. The Working Group

membership will represent diverse scientific disciplines and views.

The charter for the Working Group has been drafted. When the charter is approved, it will be filed with the appropriate Congressional committees and the Library of Congress; hard copies of this document will be made available upon request. The approved charter also will be accessible on line. The Working Group will be established as a non-discretionary federal advisory committee.

Objectives and Scope of Activities. The Secretary of Health and Human Services is responsible for ensuring the conduct of and support for epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases. The Working Group will provide assistance for this effort. The Working Group membership will provide expertise and will review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities..

Membership and Designation. The Working Group will consist of 14 voting members who represent diverse scientific disciplines and views. The composition will include seven federal members and seven non-federal public members. The federal members will consist of one or more representatives of each of the following: Office of the Assistant Secretary for Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the National Institutes of Health. The non-federal public members will consist of representatives of the following categories: physicians and other medical providers with experience in diagnosing and treating tick-borne diseases; scientists or researchers with expertise; patients and their family members; nonprofit organizations that advocate for patients with respect to tick-

borne disease. Individuals who are appointed to represent federal entities will be classified as regular government employees. The non-federal public members will be classified as special government employees. Invitations of membership will be extended to other agencies and offices of the Department of Health and Human Services and other individuals as determined by the Secretary to be appropriate and beneficial for accomplishing the mission of the Working Group.

The federal members will be appointed to serve for the duration of time that the Working Group is authorized to operate. Participation of the appointed federal members will be at the discretion of their respective agency head. The non-federal public members will be invited to serve overlapping terms of up to four years. Any non-federal public member who is appointed to fill the vacancy of an unexpired term will be appointed to serve for the remainder of that term. A non-federal public member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days. Terms of more than two years are contingent upon renewal of the charter of the Working Group.

Pursuant to advance written agreement, non-federal public members of the Working Group will receive no stipend for the advisory service that they render as members of the Working Group. However, non-federal public members will receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Working Group, as authorized by law under 5 U.S.C. 5703 for persons who are employed intermittently to perform services for the federal government and in accordance with federal travel regulations.

Estimated Number and Frequency of Meetings. The Working Group will meet not less than twice a year. The meetings will be open to the public, except as determined otherwise by the Secretary, or another official to whom authority has been delegated, in accordance with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c).

NOMINATIONS: Nominations, including self-nominations, of individuals who have the specified expertise and knowledge will be considered for appointment as public voting members of the Working Group. A nomination should include, at a minimum, the following for each nominee: (1) a letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination, and a statement from the nominee that indicates that the individual is willing to serve as a member of the Working Group, if selected; (2) the nominator's name, address, and daytime telephone number, and the address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae or resume, which should be limited to no more than 10 pages.

Every effort will be made to ensure that the Working Group is a diverse group of individuals with representation from various geographic locations, racial and ethnic minorities, all genders, and persons living with disabilities.

Individuals being considered for appointment as public voting members will be required to complete and submit a report of their financial holdings. An ethics review must be conducted to

ensure that individuals appointed as public voting members of the Working Group are not involved in any activity that may pose a potential conflict of interest for the official duties that are to be performed. This is a federal ethics requirement that must be satisfied upon entering the position and annually throughout the established term of appointment on the Working Group.

Dated: July 12, 2017.

Donald Wright

Acting Assistant Secretary for Health

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